

REMARKS

Status of the Claims

Claims 1-41 are pending. In the following pages, the comments in the Office Action are addressed in the order set forth therein.

Claim Rejections Under 35 U.S.C. §103(a)

Claims 1, 2, 10-14, 17 18, 22-29 and 41 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Gribbon et al. (1996). According to the Examiner, Gribbon et al teach a method for preserving an agent comprising: a) dissolving an agent in trehalose or sucrose at a concentration of between 1% and 50% w/v; subjection (a) to temperature and pressure conditions such that (a) loses solvent by evaporation without freezing or bubbling (page 138, section “Trehalose stabilization;” pages 140-142 section “Q-T4 Drying and Stabilization in Trehalose” and Q-T4 stabilisation in a novel drug delivery systems”; Fig 1).

Applicants have amended the claims to include the limitation of drying an active agent which at a pressure below 30mbars. Support for the amendment is found on page 11 line 11 of the specification as filed. In the claims as amended, the method of the present invention provides a method for drying an active agent which involves a pressure below 30mbars and results in preservation of the active agent, as demonstrated in the results of examples 3, 4 and 5 of the present application. There is no teaching or suggestion in Gribbons to suggest using a pressure below 30mbars or that drying a sample at such a pressure without freezing or bubbling is beneficial. Gribbons teaches critical point drying which involves much higher pressures.

Claim Rejections Under 35 U.S.C. §112

Claims 3-9, 15 16, 19-21, 30-34 and 37-40 are rejected under 35 U.S.C. 112 second paragraph as being indefinite as the claims are dependent from rejected

claims, above. Applicants have amended the claims from which these claims are dependent, putting all pending claims in condition for allowance.

Applicants request the rejections under 35 U.S.C. 103(a) and 112 second paragraph be withdrawn.

CONCLUSION

Applicants submit that given the amendments and points of distinction set forth in the Remarks, this application is now in condition for allowance. Early notice to this effect is solicited.

The Commissioner is hereby authorized to charge any fees or credit any overpayment to deposit Account No. 07-1392.

Respectfully submitted,

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